

APPENDIX A

Documents submitted on February 24, 2005

**(Attorney Docket No.: 2578-3833.9US)
(Serial No.: 10/618,526)**

MAR 0 / 2005

TRASKBRITT, PC

THE PATENT & TRADEMARK OFFICE MAILROOM DATE
STAMPED HEREON IS AN ACKNOWLEDGEMENT THAT ON THIS
DATE THE PATENT & TRADEMARK OFFICE RECEIVED:

Transmittal (1 page, in duplicate); Communication (2 pages); Copy of Fee
Transmittal submitted on November 11, 2004 (1 page); Check No. 7375 in
the amount of \$144.00; Amendment (9 pages); Declaration (2 pages with
attachments); 6 separate Terminal Disclaimers (1 page each); Check No. 7449
in the amount of \$780.00

Invention: PACKAGING SYSTEMS FOR HUMAN
RECOMBINANT ADENOVIRUS TO BE USED IN

GENE THERAPY

Applicant(s):

Fallaux et al.

Filing Date:

July 11, 2003

Serial No.:

10/618,526

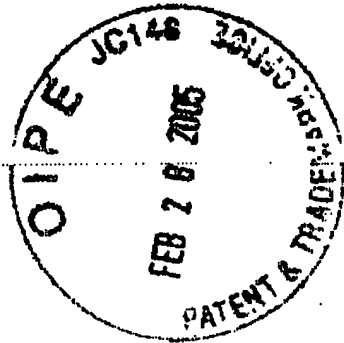
Date Sent:

February 24, 2005 via first class mail

Docket No.:

2578-3833.9US

ACT/bv





Please type and sign (do not check this box) → ☐

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/618,526
Filing Date	July 11, 2003
First Named Inventor	Fallaux et al.
Group Art Unit	1632
Examiner Name	D. Nguyen
Attorney Docket Number	2578-3833.9US

ENCLOSURES (check all that apply)

- ☒ Postcard receipt acknowledgment (attached to the front of this transmittal)
- ☒ Duplicate copy of this transmittal sheet in the event that additional filing fees are required under 37 C.F.R. § 1.116
- ☐ Preliminary Amendment
- ☐ Response to Restriction Requirement/Election of Species Requirement dated
- ☒ Amendment in response to office action dated December 1, 2004
- ☐ Amendment under 37 C.F.R. § 1.116 in response to final office action dated
- ☐ Additional claims fee - Check No. in the amount of \$
- ☐ Letter to Chief Draftsman and copy of FIGS. with changes made in red
- ☐ Transmittal of Formal Drawings
- ☐ Formal Drawings (sheets)

- ☐ Information Disclosure Statement, PTO/SB/08A; ☐ copy of cited references
- ☐ Supplemental Information Disclosure Statement; PTO/SB/08A; copy of cited references and Check No. in the amount of \$180.00
- ☐ Associate Power of Attorney
- ☐ Petition for Extension of Time and Check No. in the amount of \$
- ☐ Petition
- ☐ Fee Transmittal Form
- ☐ Certified Copy of Priority Document(s)
- ☐ Assignment Papers (for an Application)

- ☒ Terminal Disclaimers (6 separate Terminal Disclaimers and check in the amount of \$780.00)

- ☒ Other Enclosure(s) (please identify below):

Communication, Copy of Fee Transmittal submitted 11/11/2004, check in the amount of \$144 for additional claims fees, Declaration with attachments

Remarks

The Commissioner is authorized to charge any additional fees required but not submitted with any document or request requiring fee payment under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account 20-1468 during pendency of this application.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name

Allen C. Turner

Registration No. 33,041

Signature

Date

February 24, 2005

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name

Betty Vowles

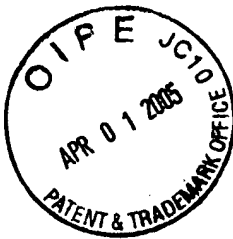
Signature

Betty Vowles

Date

February 24, 2005

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

**For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY**

Confirmation No.: 5055

Examiner: D. Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.9US

CERTIFICATE OF MAILING

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February 24, 2005
Date

Signature

Betty Vowles
Name (Type/Print)

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

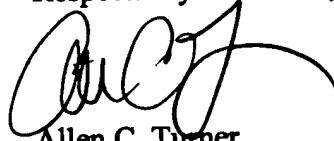
Sir:

On November 11, 2004, a fee transmittal was submitted for additional dependent claims over 20 (copy attached). Accompanying the fee transmittal was a check in the amount of \$144 for small entity fees. The filing fee for this case had been paid in the amount of \$750 for large entity fees. The applicant does not claim small entity status. The transmittal of November 11, 2004, should have been in the amount of \$288. Enclosed is a check on the amount of \$144 which should correct this clerical error.

Serial No. 10/618,526

If the amount is insufficient, please debit TraskBritt deposit account 20-1469 for any additional fee.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'ACT', with a long horizontal flourish extending to the right.

Allen C. Turner
Registration No. 33,041
Attorney for Applicant(s)
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: February 24, 2005
ACT/bv
Document in ProLaw



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Approved for use through 07/31/2005. OMB 0951-0002
Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE
class of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 144

Complete if Known

Application Number 10/818,526
Filing Date July 11, 2003
First Named Inventor Fallaux et. al.
Examiner Name To be assigned
Art Unit 1632
Attorney Docket No. 2578-3833.9US

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money ☐ Other ☐ None
Order

☐ Deposit Account:

Deposit
Account
Number

20-1489

Deposit
Account
Name

TraskBritt

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, except for the filing fee
to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	790	2001	395	Utility filing fee	
1002	350	2002	175	Design filing fee	
1003	550	2003	275	Plant filing fee	
1004	790	2004	395	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid
28	-20**	8	X	18	=	144
Independent Claims		0	X		=	0
Multiple Dependent			X		=	0

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	88	2201	44	Independent claims in excess of 3	
1203	300	2203	150	Multiple dependent claim, if not paid	
1204	88	2204	44	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$) 144

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,370	2453	685	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	680	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$0)

SUBMITTED BY

Name (Print/Type)

Allen C. Turner

Registration No.
(Attorney/Agent)

33,041

Telephone

801-532-1922

Signature

Date

November 11, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Examiner: Dave Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.9US

CERTIFICATE OF MAILING

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February 24, 2005
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Responsive to the Communication mailed December 1, 2004, please amend the referenced application as follows:

Amendments to the Specification appear on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims that begins on page 3 of this paper.

Remarks begin on page 7 of this paper.

IN THE SPECIFICATION:

Please amend paragraph number [0001] as follows:

[0001] This patent application is a continuation of patent application Serial No. 10/219,414, pending, which is a continuation of co-pending U.S. Patent Application Serial No. 10/125,751, filed April 18, 2002, which is a continuation of U.S. Patent Application Serial No. 09/506,548, filed February 17, 2000, ~~pending~~ now U.S. Patent 6,602,706, which is a divisional of U.S. Patent Application Serial No. 09/334,765, filed June 16, 1999, now U.S. Patent 6,238,893, issued May 29, 2001, which is a continuation of U.S. Patent Application Serial No. 08/793,170, filed March 25, 1997, now U.S. Patent 5,994,128, issued November 30, 1999, which ~~claims priority from~~ is a national entry of PCT International Patent Application PCT/NL96/00244, filed June 14, 1996, which itself claims priority from European Patent Application EP 95201728.3, filed June 26, 1995, and European Patent Application EP 95201611.1, filed June 15, 1995, each of which is hereby incorporated herein in its entirety by this reference.

IN THE CLAIMS:

Claims 2, 8, 13 and 17 are canceled herein. Claims 1, 3-7, 9-12, 14-16 and 18 – 28 have been amended herein. All of the pending claims are presented below. This listing of claims will replace all prior versions and listings of claims in the application. Please enter these claims as amended.

Listing of Claims:

1. (Currently amended) A An isolated adenovirus packaging cell comprising in its genome:

a first nucleic acid sequence encoding adenovirus E1A and E1B gene products; ~~wherein the cell lacks a~~ but lacking a nucleic acid sequence ~~from an encoding~~ adenovirus pIX ~~gene that can mediate homologous recombination with a second nucleic acid sequence encoding a functional or active pIX gene product.~~

2. (Canceled).

3. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein said first nucleic acid sequence comprises nucleotides 459-3510 of the human adenovirus 5 genome.

4. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of a retina cell origin.

5. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of a primary cell origin.

6. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of an embryonal cell origin.

7. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is a human cell.

8. (Canceled).

9. (Currently amended) The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is a PER.C6 cell as deposited under no. 96022940 at the European Collection of Animal Cell Cultures, ~~or a derivative thereof.~~

10. (Currently amended) The isolated adenovirus packaging cell of claim 1, further comprising a nucleic acid sequence encoding an adenovirus E2A gene product.

11. (Currently amended) The isolated adenovirus packaging cell of claim 10, wherein the adenovirus E2A gene product includes a temperature sensitive 125 mutation.

12. (Currently amended) An isolated adenovirus packaging cell comprising in its genome:

a first nucleic acid sequence encoding adenovirus E1A and E1B proteins but, ~~said cell~~ lacking a nucleic acid sequence encoding ~~from an~~ adenovirus pIX, ~~gene that can mediate homologous recombination with a second nucleic acid sequence encoding a functional or active pIX gene product.~~

13. (Canceled).

14. (Currently amended) The isolated adenovirus packaging cell of claim 12, comprising nucleotides 459-3510 of the human adenovirus 5 genome incorporated therein.

15. (Currently amended) The isolated adenovirus packaging cell of claim 12, wherein the isolated adenovirus packaging cell is of a retina cell origin.

16. (Currently amended) The isolated adenovirus packaging cell of claim 15, wherein the isolated adenovirus packaging cell is a human cell.

17. (Canceled)

18. (Currently amended) The isolated adenovirus packaging cell of claim 16, wherein the isolated adenovirus packaging cell ~~originates from~~ is a PER.C6 cell as deposited under no. 96022940 at the European Collection of Animal Cell Cultures, ~~or a derivative thereof.~~

19. (Currently amended) The isolated adenovirus packaging cell of claim 12, further comprising a nucleic acid sequence encoding an adenovirus E2A protein.

20. (Currently amended) The isolated adenovirus packaging cell of claim 19, wherein the adenovirus E2A protein includes a temperature sensitive 125 mutation.

21. (Currently amended) The isolated adenovirus packaging cell of claim 1, further comprising a recombinant expression vector derived from a human adenovirus genome, wherein said expression vector comprises an adenovirus gene encoding a pIX protein and further wherein said expression vector lacks nucleic acid sequences that overlap with said first nucleic acid sequence.

22. (Currently amended) The isolated adenovirus packaging cell of claim 10, wherein the nucleic acid sequence encoding an adenovirus E2A protein is operatively linked to an E1A-independent transcription initiation region.

23. (Currently amended) The isolated adenovirus packaging cell of claim 21, wherein the recombinant expression vector is IG.Ad.MLPI.TK shown in FIG. 12.

24. (Currently amended) The isolated adenovirus packaging cell of claim 21, wherein the recombinant expression vector is derived from a human adenovirus 5 genome from which nucleotides 459-3510 have been deleted.

25. (Currently amended) The isolated adenovirus packaging cell of claim 12, further comprising a recombinant expression vector derived from a human adenovirus genome, wherein said expression vector comprises an adenovirus gene encoding a pIX protein and further wherein said expression vector lacks nucleic acid sequence that overlaps with said first nucleic acid sequence.

26. (Currently amended) The isolated adenovirus packaging cell of to claim 19, wherein the nucleic acid sequence encoding an adenovirus E2A protein is operatively linked to an E1A-independent transcription initiation region.

27. (Currently amended) The isolated adenovirus packaging cell of claim 25, wherein the recombinant expression vector is IG.Ad.MLPI.TK shown in FIG. 12.

28 (Currently amended) The isolated adenovirus packaging cell of claim 25, wherein the recombinant expression vector is derived from a human adenovirus 5 genome from which nucleotides 459-3510 have been deleted.

REMARKS

The Office Action mailed December 1, 2004 has been received and reviewed. Claims 1 through 28 were pending in the application. All stand rejected. Claims 2, 8, 13 and 17 are to be canceled. The application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

A. Examiner Interview:

The applicants would like to thank the Examiner for the courtesy extended applicants' representatives at the interview of February 8, 2005. As discussed at the interview (and as is more thoroughly discussed herein), applicants would present the foregoing clarifying amendments to the application, which should overcome the outstanding objections and rejections, and place the application in condition for allowance. As also discussed at the interview, applicants supply herewith deposit receipt and Budapest Treaty declaration for the PER.C6 cell line. (*See, e.g.*, claims 9 and 18).

B. The Specification:

As per the Examiner's request, applicants have updated the "cross-reference" information.

C. 35 U.S.C. § 112:

The pending claims stand rejected as assertedly containing "new matter" with respect to the claims extending to cells comprising a first nucleic acid sequence that not only comprises E1A and E1B genes but also a portion of an adenovirus pIX gene. Applicants have amended the claims as discussed at the interview, and partially in view of these amendments, request that the rejection be withdrawn.

Specifically (and as discussed at the interview), applicants have amended the claims to set forth clearly that the claimed cells comprise a first nucleic acid in their genome that encodes adenoviral E1A and E1B gene products, but lacks a sequence encoding pIX. Basis for the amendment is found in various places in the as-filed specification, but specific basis can be found

in claim 8 of the application. Accordingly, this rejection should be withdrawn.

Claims 1 through 11 were rejected under 35 U.S.C. § 112 to the extent they extended beyond isolated or cultured adenovirus packaging or producer cells. As discussed at the interview, applicants have amended the claims to clearly set forth that the cells claimed in claims 1 through 11 are isolated cells useful as adenovirus packaging cells. Accordingly, this rejection should be withdrawn.

D. 35 U.S.C. §§ 102 & 103:

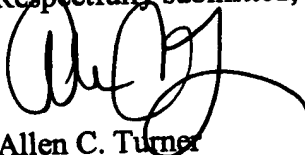
The pending claims stand rejected as assertedly being anticipated or made obvious in view of Imler, Wilson, Graham, and possibly Gregory. As discussed at the interview, none of these references discloses or makes obvious an isolated adenovirus packaging cell comprising, in its genome, a first nucleic acid sequence encoding adenovirus E1A and E1B gene products but lacking nucleic acid sequences encoding adenovirus pIX as claimed in the amended claims. Accordingly, these rejections should be withdrawn.

E. Obviousness-type Double Patenting:

The pending claims stand rejected as assertedly being obvious under the judicially created doctrine of obviousness type double patenting in view of U.S. Patents 5,994,128, 6,033,908, 6,265,212, 6,306,652, and 6,692,966 and provisionally rejected under the same doctrine in view of USSN 10/125,751 and USSN 10/219,414. Submitted herewith are appropriately executed terminal disclaimers that should overcome the rejections.

In view of the foregoing, the application should be in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

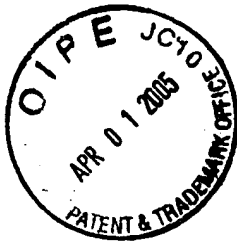
Respectfully submitted,



Allen C. Turner
Registration No. 33,041
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Enclosures: Budapest Treaty Declaration
Terminal Disclaimers

Date: February 24, 2005

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****In re Application of:**

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

**For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY**

Confirmation No.: 5055

Examiner: D. Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.9US

DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ronald Brus, hereby certify that I am the Chief Executive Officer of Crucell Holland BV ("Crucell") and declare that:

1. Crucell is the assignee of record of U.S. Patent Application Serial No. 10/618,526.
2. According to the deposit receipt, a deposit of the PER.C6 cell line was made, under ECACC deposit number 96022940, under the provisions of the Budapest Treaty with the Centre for Applied Microbiology and Research Authority (European Collection of Animal Cell

Serial No. 10/618,526

Cultures), Porton Down, Salisbury, Wiltshire SP4, OJG, United Kingdom, an International Depository Authority, on February 29, 1996.

3. On behalf of Crucell, I state that all restrictions upon public access to the deposit (except those permitted by 37 C.F.R. § 1.808(b)) will be irrevocably removed upon the grant of a U.S. patent on this U.S. patent application, and the deposit will be replaced if viable samples cannot be dispensed by the depository.

4. According to the deposit receipt, the deposit was accepted by the International Depository Authority, effective at least as early as February 29, 1996.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent.

Date: February 23, 2005


Dr. Ronald Brus



CAMR

Today's Research
Tomorrow's Health

Microbiological Research Authority

14-12-1999 10:32

Introgene

+31 715248704 P.02/05

Centre for Applied Microbiology and Research

This document certifies that CELL LINE

(Deposit ref 96022940) has been accepted

as a patent deposit, in accordance with

The Budapest Treaty of 1977,

with the European Collection of Cell Cultures on

29th February 1996

Dr. Alan Doyle,
Head, Cell Resources.

APPENDIX 3

page 14

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

INTROGENE BV
PO Box 3271
2280 GG Rijswijk
The NetherlandsNAME AND ADDRESS
OF DEPOSITORRECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: PER C6	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 96022940
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by:	
<input checked="" type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on 29/2/1996 (date of the original deposit) ¹	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depositary Authority on (date of the original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr A Doyle EMCCU, CAMH Porton Down Address: Millisbury SP4 0JC	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 27.2.97

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired.

Appendix 3
page 24BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
INTROGENE BV
PO Box 3271
2280 GG Rijswijk
The Netherlands

VIABILITY STATEMENT
issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY STATEMENT
IS ISSUED

I. DEPOSITOR.	II. IDENTIFICATION OF THE MICROORGANISM
Name: Introgene BV Address: PO Box 3271 2280 GG Rijswijk The Netherlands	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 96022940 Date of the deposit or of the transfer: 29th February 1996
III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on ¹ <input checked="" type="checkbox"/> viable ³ <input type="checkbox"/> no longer viable	

- ¹ Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- ² In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- ³ Mark with a cross the applicable box.

Appendix 3
page 25IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED⁴

V. INTERNATIONAL DEPOSITARY AUTHORITY

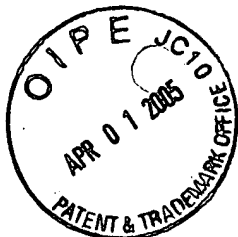
Name: Dr A Doyle

Address: ECACC, CAMR
Porton Down
Salisbury
SP4 0JGSignature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Date:

27.2.97

⁴ Fill in if the information has been requested and if the results of the test were negative.



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Docket Number (Optional)
2578-3833.9US

In re Application of: Fallaux et al.

Application No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

The owner, Cruce Holland B.V., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 5,994,128. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

Signature

Feb. 24, 2005

Date

Allen C. Turner

Typed or printed name
Reg. No. 33,041

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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Docket Number (Optional)
2578-3833.9US

In re Application of: Fallaux et al.

Application No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

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In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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Signature

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Docket Number (Optional)
2578-3833.9US

In re Application of: Fallaux et al.

Application No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

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2578-3833.9US

In re Application of: Fallaux et al.

Application No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

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Allen C. Turner

Typed or printed name

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